UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

APR 2 2010

CERTIFIED MAIL-RETURN RECEIPT REQUESTED
Article number: 7003 2260 0000 3242 8166

Bill Eversgerd, Vice President, Plant Operations
Epic Pharma, LLC
227-15 N. Conduit Ave.
Laurelton, NY 11413

NOTICE OF VIOLATION

RCB I.D. #10-3007-0000-07

Re: Epic Pharma, LLC
EPA I.D. No.: NYD001212752
Notice of Violation
RCRA Information Request

Dear Mr. Eversgerd:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 and the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. §§ 6901 et seq. (commonly referred to as "RCRA").

Pursuant to RCRA, as amended by HWSA, EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste set forth in 40 Code of Federal Regulations ("C.F.R.") Parts 260 through 268 and 270 through 272.

On or about August 18, 2009, a duly authorized representative of EPA conducted a RCRA compliance evaluation inspection of Epic Pharma, LLC, located at 227-15 N. Conduit Ave., Laurelton, New York, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. This letter addresses the solid and hazardous waste violations found during that inspection, and requests additional information regarding the management of solid and hazardous wastes at your facility.

Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), provides that the EPA Administrator may, if certain criteria are met, authorize a state to operate a hazardous waste and used oil management program in lieu of the federal program. The State of New York is authorized by EPA to conduct a hazardous waste program under Section 3006 of RCRA, 42 U.S.C. § 6926. Section 3008(a) of the Act, 42 U.S.C. § 6928 authorizes EPA to enforce the provisions of the authorized State program. Section 3008(a)(2) of the Act, 42 U.S.C. § 6928(a)(2), authorizes EPA to enforce the authorized regulations of a state. Consequently, EPA has the authority to enforce the regulations comprising the State Program.

This correspondence includes a Notice of Violation ("NOV"), issued pursuant to Sections 3007 and 3008 of RCRA, 42 U.S.C. §§ 6927 and 6928, and an Information Request issued pursuant to Section 3007 of RCRA. All questions and requests for information contained within this correspondence are issued pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. Pursuant to that section, EPA hereby requires that you provide the information requested in Enclosures I and II. Please use the instructions and definitions included in Enclosure III and complete and submit with your response the Certification of Answers in Response to Requests for Information in Enclosure IV.

Please provide the information requested no later than thirty (30) calendar days from receipt of this letter. Requests for additional time must be justified and must be made within ten (10) calendar days of receipt of this letter. The response must be signed by a responsible official of Epic Pharma, LLC or other agent who is authorized to respond on behalf of Epic Pharma, LLC.

Your responses to the requests for information contained within Enclosure I (Notice of Violation) and in Enclosure II (Information Request) must be mailed along with your Certification of Answers in Response to Requests for Information (Enclosure IV) to the following addressee:

Mr. Sam Kerns
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway, 22nd Floor
New York, New York 10007-1866

For ease of review, please provide your answers in a format which is keyed to the questions as outlined in Enclosure II to this letter.

Failure to respond to this letter truthfully and accurately within the time provided may subject you to sanctions authorized by federal law, including but not limited to a potential enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. 6928. Please also note that all information you provide may be used in an administrative, civil judicial, or criminal action. Neither the issuance of this joint Notice of Violation and RCRA Information Request nor your compliance with its terms shall preclude EPA from taking formal enforcement action against you, and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

You may, if you so desire, assert a business confidentiality claim covering all or part of the information requested. The claim may be asserted by placing on (or attaching to) the information at the time it is submitted, a cover sheet, stamped or typed with the legend, or other suitable form of notice, such as "trade secret," "proprietary," or "company confidential." The claim should set forth the information requested in 40 C.F.R. § 2.204(e)(4). Information covered by such a claim will be disclosed by EPA only to the extent permitted by, and by means of

procedures set forth in, 40 C.F.R. Part 2. EPA will review the information to determine the extent of confidentiality of the information, and may, at its discretion, challenge the confidentiality claim pursuant to the procedures set forth at 40 C.F.R. Part 2. If no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to you.

This request for information is not subject to the requirements of the Paperwork Reduction Act of 1980, as amended, 44 U.S.C. § 3501 et seq.

If you have any questions regarding this matter, please contact Mr. Kerns at (212) 637-4062 or *kerns.sam@.epa.gov*. In addition, you may consult the EPA website [http://www.epa.gov] which includes, among other resources, RCRA Online [http://www.epa.gov/epawaste/inforesources/online/index.htm], a database designed to enable users to locate documents, including publications and other outreach materials, which cover a wide range of RCRA issues.

Sincerely yours,

George C. Meyer, P.E., Chief
RCRA Compliance Branch

Enclosures: Enclosure I – Notice of Violation
Enclosure II – RCRA § 3007 Information Request
Enclosure III – Instructions and Definitions
Enclosure IV – Certification of Answers

cc: Thomas J. Killeen, Chief
Inspection & Compliance Section
Division of Solid & Hazardous Materials
New York State Department of Environmental Conservation

bcc: Leonard Voo, 2DECA/RCB/HWCS
Charles Zafonte, 2DECA/CAPSB
Norm Rost, 2DECA/RCB/HWCS
RCRA Files, 2OPM/ISS
Sam Kerns, 2DECA/RCB/HWCS

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ENCLOSURE I

Notice of Violation

Epic Pharma, LLC
EPA I.D. No.: NYD001212752

On or about August 18, 2009, a duly authorized representative of EPA conducted an inspection of Epic Pharma, LLC located at 227-15 N. Conduit Ave., Laurelton, New York, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. Based on the findings of this inspection, EPA has determined that Epic Pharma, LLC violated the regulations listed below.

1. 6 N.Y.C.R.R. § 373-3.9(e) [40 C.F.R. § 265.174] had been violated. Section 373-3.9(e) [and Section § 265.174 of the federal regulations] states the following: At least weekly, the owner or operator must inspect areas where containers are stored, looking for leaking containers and for deterioration of containers and the containment system caused by corrosion or other factors.

   At the time of this inspection, the facility could not demonstrate it had performed weekly inspections. No weekly inspection log or other documentation of compliance with this requirement was available. Further, an acid carboy in the 90-day storage area was observed to be bulging, an indication of a possible reaction and a potential indication that it had not been recently inspected.

2. 6 N.Y.C.R.R. § 373-3.2(g)(3) [40 C.F.R. § 265.16(c)] has been violated. Section 373-3.2(g)(3) [and Section 265.16(c) of the federal regulations] requires that facility personnel must take part in an annual review of the initial training that teaches them to perform their duties in a way that ensures the facility's compliance with RCRA requirements.

   Personnel at the facility have not taken part in an annual review of the training as required by RCRA. At the time of this inspection, facility representatives told the inspector that the written description of the type and amount of both introductory and continuing training that will be given to each person filling a position related to hazardous waste management is provided in eight of the facility's approximately 300 Standard Operating Procedures and two other courses. During this inspection, it was observed that some of these required RCRA training elements were provided in 2006 and 2008, but some had not been provided since 2004 when a NYSDEC enforcement action raised this same issue. These RCRA training elements are listed below (with the date of the most recent training given in parenthesis):

   - WH-22, Storm Water Accidental Spill Prevention Plan (11/06)
   - QC-021, QC Chemical Hygiene Plan (9/04)
   - QC-024, Lab Chemical Spill Procedure (5/04)
   - QC-035, Laboratory Solutions (11/08)

- QC-051, Laboratory Chemicals (11/08)
- QC-059, Annual Certification for Laboratory Personnel (11/08)
- G-039, Respiratory Protection Program (9/04 and 6/08)
- G-045, Hazardous Communication Program for Plant (non-lab operations), 10/04
- 8-Hour Hazwoper, RCRA, and Hazmat Course (given every two years, 10/20/06)
- RCRA and Contingency Plan Training (8/04)

Despite the training dates given above, a document provided to the inspector entitled "Training and Exercises/Drills" made it clear that training was intended to be annual.

3. 6 N.Y.C.R.R. § 373-3.4(e) [40 C.F.R. § 265.54] has been violated. Section 373-3.4(e) [and Section 265.54 of the federal regulations] requires that the contingency plan must be reviewed, and immediately amended, if necessary, whenever:

(1) applicable regulations are revised;
(2) the plan fails in an emergency;
(3) the facility changes – in its design, construction, operation, maintenance, or other circumstances – in a way that materially increases the potential for fires, explosions, or releases of hazardous waste or hazardous waste constituents, or changes the response necessary in an emergency;
(4) the list of emergency coordinators changes; or
(5) the list of emergency equipment changes.

Because of a change in emergency coordinators and response team members, a change in ownership, and a name change, the 9/04 Integrated Contingency Plan must be updated. The plan was submitted to the local authorities on 9/24/04 when Eon Labs Manufacturing, Inc. operated the facility.

ENCLOSURE II

Information Request

Epic Pharma, LLC
EPA I.D. No.: NYD001212752

On or about August 18, 2009, a duly authorized representative of EPA conducted an inspection of Epic Pharma, LLC located at 227-15 N. Conduit Ave., Laurelton, New York, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. In follow-up to that inspection, the information requested below is needed to determine the compliance status of your facility. **Please provide the information requested no later than thirty (30) calendar days from receipt of this letter. Requests for additional time must be justified and must be made within ten (10) calendar days of receipt of this letter.**

Request 1

In regards to Violations 1 through 4 cited in the above Notice of Violation (Enclosure I), please provide either a rebuttal or a description of the actions taken to correct these violations along with documentation that compliance has been achieved, such as photographs of corrected violations and/or photocopies of relevant documents.

Request 2

Epic Pharma uses a Bulb Eater lamp crusher, Model 55-VRS (with emissions control), manufactured by Air Cycle Group to crush used fluorescent lamps.

a. Please provide a copy of the owner's manual for this Bulb Eater lamp crusher.

b. Please provide any documentation which demonstrates that the filters in the lamp crusher were changed in accordance with the instructions in the owner's manual. If they were not changed in accordance with the instructions in the owner's manual, please describe how often the filters in this lamp crusher were changed and provide any records you may have.

c. Please list any personal protective equipment that was worn by personnel when changing any of the filters.

d. Please describe how spent filters were stored at your facility after they were removed from service. If they were not stored as indicated in the owner's manual, please explain why.

e. If the spent filters were not placed on top of the crushed glass once a drum was full and shipped with the drum of crushed lamps, please provide all analytical results and/or documentation used in determining whether or not the spent filters are hazardous waste.

If generator knowledge was used to determine whether or not the spent filters are hazardous waste, please provide a narrative description which details the knowledge employed in making such a determination.

f. Please provide copies of any documentation for the treatment or disposal of these spent filters during the period August 2006 through August 2009 (inclusive), including copies of hazardous waste manifests, non-hazardous waste manifests, bills of lading, recycling certificates, etc. If no documentation exists, please provide a narrative description of how the spent filters were disposed.

ENCLOSURE III

INSTRUCTIONS AND DEFINITIONS

In responding to this Request for Information, apply the following instructions and definitions:

1. The signatory should be an officer or agent who is authorized to respond on behalf of the company or facility.

2. A complete response must be made to each individual point in this request for information. Identify each response with the number of the request to which it is addressed.

3. In preparing your response to each request, consult with all present and former employees and agents of the company or facility who you have reason to believe may be familiar with the matter to which the request pertains.

4. In responding to each request, identify all contributing sources of information.

5. If you are unable to respond in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any request, state that person's name and last known address and phone number and the reasons for your belief.

6. If you cannot provide a precise response to any request, please approximate and state the reason for your inability to be specific.

7. For each document produced in response to this Request for Information, indicate on the document or in some other reasonable manner, the number of the request to which it applies.

8. If anything is deleted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion.

9. If a document is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.

10. The company and/or facility for the purposes of this Request for Information is the one to which this request for information is addressed.

11. Hazardous waste shall be defined for the purposes of this Request for Information as that term is defined in Section 1004(5) of RCRA, as amended, 42 U.S.C. Part 6903(5) and in 40 C.F.R., Section 261.3.

12. Manage shall be defined for the purposes of this Request for Information as a market, generate, treat, store, dispose or otherwise handle.

13. Standards applicable to transporters of hazardous waste shall be those as established in 40 C.F.R. Part 263.

14. Hazardous constituents shall be defined as those substances listed in 40 C.F.R. Part 261, Appendix VIII.

ENCLOSURE IV

Epic Pharma, LLC
EPA I.D. No.: NYD001212752

Certification of Answers to Responses to Request for Information

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document (response to EPA Request for Information) and all documents submitted herewith, that the submitted information is true, accurate and complete, and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

_____
NAME (print or type)

_____
TITLE (print or type)

_____
SIGNATURE

_____
DATE